K091284

510(k) Summary for VisuCal-F Frozen Calibrator Plasma (Summary of Safety and Effectiveness)

This summary of 510(k) safety and effectiveness information is being submitted in accordance with the requirements of SMDA 1990 and 21 CFR 807.92.

Submitted By:

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OCT 2 8 2009

Contact Person:

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Summary Prepared: October 20, 2009

Name of the Device: VisuCal-F Frozen Calibrator Plasma
Common Name: Plasma Calibrator

Classification of Device: Class II
21 CFR 864.5425, Multipurpose Systems for In Vitro Coagulation Studies
Subpart H, Hematology Kits and Packages
Product Code: GGN

Predicate Devices: Cryocheck Normal Reference Plasma, K952622
Precision Biologic
and
Standard Human Plasma, K023141
Dade Behring Inc.

Device Description: The VisuCal-F Frozen Calibrator Plasma is a pool of normal citrated human plasma collected from a minimum of 20 donors, buffered with 0.02 M HEPES buffer, dispensed and rapidly frozen.

Device Intended Use: The VisuCal-F Frozen Calibrator Plasma is intended for use in the calibration of coagulation and fibrinolysis assays.

Comparison to Predicate Device:

A technical comparison of the proposed device and the predicate devices is illustrated in the following table:

	VisuCal-F Frozen Calibrator Plasma (Proposed Device)	Precision Biologic Cryocheck Normal Reference Plasma (Predicate Device)	Dade Behring Standard Human Plasma (Predicate Device)
Intended Use	For use in the calibration of coagulation and fibrinolysis assays	For use in the *in vitro* quantification of hemostatic parameters in human plasma	For the calibration of coagulation and fibrinolysis tests
Analytes	Fibrinogen, Coagulation factors II, V, VII,VIII, IX, X, XI, XII, von Willebrand Factor antigen, Ristocetin Cofactor, Protein S activity Protein S Total antigen, Protein C activity, Protein C antigen, antithrombin activity, α2-antiplasmin, plasminogen	Fibrinogen, Coagulation factors II, V, VII,VIII, IX, X, XI, XII, von Willebrand Factor antigen, Ristocetin Cofactor, Protein S activity, Protein S Total antigen, Protein C activity, Protein C antigen, antithrombin activity, α-2-antiplasmin (also known as plasmin inhibitor), plasminogen, Factor XIII, Free Protein S antigen, antithrombin antigen	Prothrombin Time (PT), Fibrinogen, Coagulation factors II, V, VII,VIII, IX, X, XI, XII, XIII, von Willebrand Factor antigen, Ristocetin Cofactor, Protein S activity, Protein C activity, antithrombin activity, α2-antiplasmin, plasminogen, C-1 inhibitor, Total Complement Activity
Traceability of Calibrator Plasma	Value assignments traceable to SSC/ISTH Secondary Coagulation Standard, where available, which is calibrated against WHO International Standards	Value assignments traceable to SSC/ISTH Secondary Coagulation Standard, where available, which is calibrated against WHO International Standards	Value assignments traceable to WHO International Standards, where available
Matrix	Citrated human plasma	Citrated human plasma	Citrated human plasma
Format	Frozen	Frozen	Lyophilized
Open-Vial Stability	8 hours at 2-8°C except Protein S which is stable for 4 hours at 2-8°C	8 hours at 2-8°C	4 hours at +15 to +25°C 4 weeks at -20°C

Conclusion: The VisuCal-F Frozen Calibrator Plasma is substantially equivalent to the Precision Biologic Cryocheck Normal Reference Plasma and Dade Behring Standard Human Plasma based on similar intended use, product matrix and performance. To our knowledge, any differences, including analytes tested in the predicate devices but not in the proposed device, do not affect the safety and effectiveness of the proposed device.

510(k) Summary for VisuCon-F Frozen Normal Control Plasma (Summary of Safety and Effectiveness)

This summary of 510(k) safety and effectiveness information is being submitted in accordance with the requirements of SMDA 1990 and 21 CFR 807.92.

Submitted By:

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Contact Person:

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Summary Prepared: September 9, 2009

Name of the Device: VisuCon-F Frozen Normal Control Plasma
Common Name: Normal Control Plasma

Classification of Device: Class II
21 CFR 864.5425
Subpart H, Hematology Kits and Packages
Product Code: GGN

Predicate Device: Reference Control Normal (Reference Check), K013708
Precision Biologic

Device Description: The VisuCon-F Frozen Normal Control Plasma is a pool of normal citrated human plasma collected from a minimum of 20 donors, buffered with 0.02 M HEPES buffer, dispensed and rapidly frozen.

Device Intended Use: The VisuCon-F Frozen Normal Control Plasma is intended for use in the quality control of coagulation assays in the normal range.

Comparison to Predicate Device:
A technical comparison of the proposed device and the predicate device is illustrated in the following table:

	VisuCon-F Frozen Normal Control Plasma (Proposed Device)	**Precision Biologic Reference Control Normal (Predicate Device)**
Intended Use	For the quality control of coagulation assays in the normal range	For controlling the accuracy of quantitative hemostasis assays in the normal range
Analytes	Fibrinogen, Coagulation factors II, V, VII,VIII, IX, X, XI, XII, Protein S activity, Protein C activity, antithrombin activity	Fibrinogen, Coagulation factors II, V, VII,VIII, IX, X, XI, XII, XIII, von Willebrand Factor antigen, Ristocetin Cofactor, Prekallikrein, Protein S (activity, total antigen,

		free antigen), Protein C (activity, antigen), antithrombin (activity, antigen), α2-antiplasmin, plasminogen
Traceability of Calibrator Plasma	Value assignments traceable to SSC/ISTH Secondary Coagulation Standard, where available, which is calibrated against WHO International Standards	Value assignments traceable to SSC/ISTH Secondary Coagulation Standard, where available, which is calibrated against WHO International Standards
Matrix	Citrated human plasma	Citrated human plasma
Format	Frozen	Frozen
Open-Vial Stability	8 hours at 2-8°C	8 hours at 2-8°C

Conclusion: The VisuCon-F Frozen Normal Control Plasma is substantially equivalent to its predicate device, Precision Biologic Reference Control Normal, based on similar intended use, product matrix and performance. To our knowledge, any differences, such as analytes tested, do not affect the safety and effectiveness of the proposed device.

510(k) Summary for VisuCon-F Frozen Abnormal Control Plasma (Summary of Safety and Effectiveness)

This summary of 510(k) safety and effectiveness information is being submitted in accordance with the requirements of SMDA 1990 and 21 CFR 807.92.

Submitted By:

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Summary Prepared: September 9, 2009

Name of the Device: VisuCon-F Frozen Abnormal Control Plasma
Common Name: Abnormal Control Plasma

Classification of Device: Class II
21 CFR 864.5425
Subpart H, Hematology Kits and Packages
Product Code: GGN

Predicate Device: Cryocheck Abnormal 1 Reference Control, K952624
Precision Biologic

Device Description: The VisuCon-F Frozen Abnormal Control Plasma is a pool of normal citrated human plasma collected from a minimum of 20 donors, diluted to defined concentrations, buffered with 0.02 M HEPES buffer, dispensed and rapidly frozen.

Device Intended Use: The VisuCon-F Frozen Abnormal Control Plasma is intended for the quality control of coagulation assays in the borderline pathological range.

Comparison to Predicate Device:
A technical comparison of the proposed device and the predicate device is illustrated in the following table:

	VisuCon-F Frozen Abnormal Control Plasma (Proposed Device)	**Precision Biologic Abnormal 1 Reference Control (Predicate Device)**
Intended Use	For the quality control of coagulation assays in the borderline pathological range	For controlling the accuracy of quantitative assays in the borderline pathological range
Analytes	Fibrinogen, Coagulation factors II,	Fibrinogen, Coagulation factors II,

	V, VII,VIII, IX, X, XI, XII, Protein S activity, Protein C activity, antithrombin activity	V, VII,VIII, IX, X, XI, XII, XIII, von Willebrand Factor antigen, Ristocetin Cofactor, Prekallikrein, Protein S (activity, total antigen, free antigen), Protein C (activity, antigen), antithrombin (activity, antigen), α2-antiplasmin, plasminogen
Traceability of Calibrator Plasma	Value assignments traceable to SSC/ISTH Secondary Coagulation Standard, where available, which is calibrated against WHO International Standards	Value assignments traceable to SSC/ISTH Secondary Coagulation Standard, where available, which is calibrated against WHO International Standards
Matrix	Citrated human plasma	Citrated human plasma
Format	Frozen	Frozen
Open-Vial Stability	8 hours at 2-8°C	8 hours at 2-8°C

Conclusion: The VisuCon-F Frozen Abnormal Control Plasma is substantially equivalent to the predicate device, Precision Biologic Cryocheck Abnormal 1 Reference Control, based on similar intended use, product matrix and performance. To our knowledge, any differences, such as analytes tested, do not affect the safety and effectiveness of the proposed devices.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Food and Drug Administration
10903 New Hampshire Avenue
Document Mail Center - WO66-G609
Silver Spring, MD 20993-0002

Affinity Biologicals Inc.
Ms. Denise Foulon
Scientific Director
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OCT 2 8 2009

Re: k091284
Trade/Device Name: VisuCal-F frozen calibrator, VisuCon-F frozen normal control and VisuCon-F frozen abnormal control plasmas
Regulation Number: 21 CFR 864.5425
Regulation Name: Multipurpose systems for in vitro coagulation studies
Regulatory Class: Class II
Product Code: GGN, JIX
Dated: September 9, 2009
Received: September 10, 2009

Dear Ms. Foulon:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to such additional controls. Existing major regulations affecting your device can be found in Title 21, Code of Federal Regulations (CFR), Parts 800 to 895. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Parts 801 and 809); medical device reporting (reporting of

medical device-related adverse events) (21 CFR 803); and good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820). This letter will allow you to begin marketing your device as described in your Section 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific advice for your device on our labeling regulation (21 CFR Parts 801 and 809), please contact the Office of *In Vitro* Diagnostic Device Evaluation and Safety at (301) 796-5450. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21 CFR Part 807.97). For questions regarding the reporting of adverse events under the MDR regulation (21 CFR Part 803), please go to http://www.fda.gov/MedicalDevices/Safety/ReportaProblem/default.htm for the CDRH's Office of Surveillance and Biometrics/Division of Postmarket Surveillance.

You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/cdrh/industry/support/index.html.

Sincerely yours,

Maria M. Chan

Maria M. Chan, Ph.D.
Director
Division of Immunology and Hematology Devices
Office of In Vitro Diagnostic Device Evaluation and Safety
Center for Devices and Radiological Health

Enclosure

Indications For Use Statement

510(k) Number (if known): K091284

Device Name: VisuCal-F Frozen Calibrator Plasma

Indications for Use:

The VisuCal-F Frozen Calibrator plasma is intended for use in the calibration of coagulation and fibrinolysis assays including the following: fibrinogen (Clauss Method), coagulation factors II, V, VII, VIII, IX, X, XI, XII, antithrombin activity, alpha-2-antiplasmin, plasminogen, Protein C activity and antigen, Protein S activity and total antigen and von Willebrand factor antigen and Ristocetin Cofactor.

Prescription Use √ **AND/OR** Over-The-Counter Use _____
(Part 21 CFR 801 Subpart D) (21 CFR 807 Subpart C)

(PLEASE DO NOT WRITE BELOW THIS LINE - CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of In Vitro Diagnostic Devices (OIVD)

Division Sign-Off

Office of In Vitro Diagnostic
Device Evaluation and Safety

510(k) 091284

Indications For Use Statement

510(k) Number (if known): K091284

Device Name: VisuCon-F Frozen Abnormal Control Plasma

Indications for Use:

The VisuCon-F Frozen Abnormal Control plasma is intended for use in the quality control of coagulation assays in the borderline pathological range for the following parameters: fibrinogen (Clauss Method), coagulation factors II, V, VII, VIII, IX, X, XI, XII, antithrombin activity, Protein C activity and Protein S activity.

Prescription Use √ **AND/OR** Over-The-Counter Use _____
(Part 21 CFR 801 Subpart D) (21 CFR 807 Subpart C)

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Division Sign-Off

Office of In Vitro Diagnostic
Device Evaluation and Safety

510(k) 091284

Indications For Use Statement

510(k) Number (if known): K091284

Device Name: VisuCon-F Frozen Normal Control Plasma

Indications for Use:

The VisuCon-F Frozen Normal Control plasma is intended for use in the quality control of coagulation assays in the normal range for the following parameters: fibrinogen (Clauss Method), coagulation factors II, V, VII, VIII, IX, X, XI, XII, antithrombin activity, Protein C activity and Protein S activity.

Prescription Use √ **AND/OR** Over-The-Counter Use _____
(Part 21 CFR 801 Subpart D) (21 CFR 807 Subpart C)

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Concurrence of CDRH, Office of In Vitro Diagnostic Devices (OIVD)

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Device Evaluation and Safety

510(k) 091284